4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-1168]

Generic Drug User Fee Amendments of 2012; September 2014 Public Hearing on Policy Development; Reopening of Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the reopening of the docket to solicit public comment on certain topics related to implementation of the Generic Drug User Fee Amendments of 2012 (GDUFA) and the GDUFA Commitment Letter that accompanies the legislation. A public hearing in September 2014 provided an opportunity for public input on future policy priorities. FDA is seeking additional written comments from all interested parties, including, but not limited to, regulated industry, consumers, patients, caregivers, health care professionals, and patient groups.

DATES: Submit electronic or written comments by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Giaquinto, Office of Generic Drugs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New

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SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) (the Hatch-Waxman Amendments) amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act). The Hatch-Waxman Amendments created section 505(j) of the FD&C Act (21 U.S.C. 355(j)), which established the abbreviated new drug application (ANDA) approval pathway, which allows lower-priced generic versions of previously approved innovator drugs to be approved and marketed.

On July 9, 2012, GDUFA was signed into law by the President to help speed the delivery of safe and effective generic drugs to the public and to reduce costs to industry. Under GDUFA, FDA agreed to certain obligations as laid out in the GDUFA Commitment Letter that accompanies the legislation.[1] To support these obligations, FDA is developing numerous guidance documents. At the time of the September 2014 public hearing, FDA had developed the following draft guidances for industry:[2]

- "ANDA Submissions--Content and Format of Abbreviated New Drug Applications"

- "ANDA Submissions--Refuse to Receive for Lack of Proper Justification of Impurity Limits"

[1] See Generic Drug User Fee Act Program Performance Goals and Procedures (GDUFA Commitment Letter) for fiscal years 2013 through 2017, available at http://www.fda.gov/downloads/ForIndustry/UserFees/GenericDrugUserFees/UCM282505.pdf).

[2] The draft guidance documents referenced in this document are available on the FDA Drugs guidance Web page at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.

- "ANDA Submissions--Amendments and Easily Correctable Deficiencies Under GDUFA"

- "ANDA Submissions--Prior Approval Supplements Under GDUFA"

- "Controlled Correspondence Related to Generic Drug Development"

II. Purpose and Scope of the September 2014 Public Hearing

A. GDUFA Implementation: Draft Guidance Documents

The purpose of the public hearing was to: (1) Solicit public comment on the five draft guidance documents described in section I that FDA had issued to facilitate implementation of GDUFA and (2) recommend future policy priorities, including recommendations for additional guidance topics to facilitate GDUFA implementation. We continue to solicit comments from interested members of the public, including industry, consumers, patient groups, caregivers, and health care professionals, on the following topics related to GDUFA implementation guidances:

- Are there comments on the five guidances described in section I?
- Are there GDUFA implementation issues related to the five draft guidances described in section I that have not been addressed?
- What other GDUFA implementation topics need the development of guidance?
- Are there any topics or issues related to generic drug development other than those related to GDUFA implementation that need the development of guidance?

B. GDUFA Implementation Related to Generic Drug Exclusivity

Another purpose of the hearing was to solicit feedback on issues that may arise in FDA's consideration of 180-day exclusivity provided for in section 505(j)(5)(B)(iv) of the FD&C Act.

Timing of ANDA approval is directly affected by an applicant's eligibility for 180-day exclusivity, and thus FDA's consideration of any issues related to 180-day exclusivity is a component of approval actions. FDA decisions regarding 180-day exclusivity are fact-specific, and the facts that have the potential to determine eligibility for exclusivity may shift up to the time when an ANDA that is eligible for 180-day exclusivity, or another ANDA referencing the same listed drug, is ready for approval.

With the enactment of GDUFA, FDA will take actions on pending applications consistent with the timeframes agreed upon in the GDUFA Commitment Letter. During the hearing, we sought input on possible processes FDA might introduce under GDUFA for making determinations on 180-day exclusivity, as described in the following questions:

- Should FDA's consideration of eligibility for 180-day exclusivity for a specific drug product be a public process, including consideration of whether a first applicant has forfeited its eligibility for exclusivity under section 505(j)(5)(D) of the FD&C Act? If a public process is advisable, would it be so in all instances, or is there a subset of circumstances in which the process should be public? Also, what administrative mechanisms would best facilitate such a process?
- Legal challenges to FDA's decisions on 180-day exclusivity often must be resolved on an expedited basis that can be inconvenient for the parties and the court. What legal or regulatory mechanisms, if any, are available to better facilitate FDA's determination of and orderly resolution of sponsors' challenges to 180-day exclusivity determinations?
- Are there other topics related to 180-day exclusivity on which you would like to comment?
- Are there topics related to 180-day exclusivity that would benefit from FDA guidance?

We continue to seek comment on these topics. When submitting input on the questions provided in this notice, we encourage commenters to consider FDA's statutory and regulatory authorities, including any restrictions on FDA's authority to disclose certain information related to unapproved ANDAs.

C. GDUFA Implementation and Potential First Generics

At the public hearing, we also sought comment on meeting the goals of the GDUFA Commitment Letter with regard to the "first generics" review prioritization category. Subsequent to that hearing, the Agency opened a separate, dedicated docket, Docket No. FDA-2014-N-1741, seeking comment on "first generic" criteria, as described in the Federal Register notice "Proposed Criteria for 'First Generic' Submissions for Purposes of Abbreviated New Drug Application Review Prioritization Under the Generic Drug User Fee Amendments; Establishment of a Public Docket." This docket opened on November 19, 2014, and closed on December 19, 2014. We are no longer seeking comment on the "first generic" review prioritization category at this time.

III. How to Submit Comments

Interested persons may submit either electronic comments regarding this document to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

Dated: February 2, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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